MAY 31 2002

Premarket Notification (510(k)) Summary

510(k) Number: K021563

Product Name: IntraCoil® Self-expanding Peripheral Stent

Common Name: Tracheal prosthesis

Class: II per 21 CFR 878.3720 (tracheal prosthesis)

Submitter's Name:
IntraTherapeutics, Inc.
651 Campus Drive
St. Paul, MN 55112

Official Contact:
Maria Brittle
Regulatory Affairs Manager
Telephone: 651-697-2018
Fax: 651-697-4808

Summary Preparation Date: May 10, 2002

This summary is provided in compliance with section 513(I)(3)(A) of the Act and summarizes the safety and effectiveness information contained in this premarket notification submission. Substantial equivalence is claimed to the IntraCoil™ Self-expanding Peripheral Stent, K990221/K001257.

The IntraCoil™ Stent is a self-expanding nickel-titanium (Nitinol) coil premounted on a delivery catheter. The stent is provided in diameters 4 to 8 mm, and lengths of 40 and 60 mm. The intended use is "in the treatment of bronchial strictures produced by malignant neoplasms or in benign strictures after all alternative therapies have been exhausted." Upon deployment the stent expands to conform to the bronchial lumen surface.

This 510(k) covers addition of the 8 x 60 mm stent. Otherwise, the device is identical to the IntraCoil™ Stent as previously cited. A subset of the *in vitro* performance tests conducted for K990221/K001257, and relevant to the modification, were repeated for design verification and product validation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 31 2002

Ms. Maria Brittle
Regulatory Affairs Manager
IntraTherapeutics, Inc.
651 Campus Drive
St. Paul, MN 55112

Re: K021563
Trade/Device Name: IntraCoil® Self-expanding Peripheral Stent
Regulation Number: 878.3720
Regulation Name: Tracheal prosthesis
Regulatory Class: II
Product Code: JCT
Dated: May 10, 2002
Received: May 13, 2002

Dear Ms. Brittle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost
for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K021563

Device Name: IntraCoil® Self-expanding Peripheral Stent

Indications for Use:

The IntraCoil® Self-expanding Peripheral Stent is indicated for use in the treatment of bronchial strictures produced by malignant neoplasms, or in benign strictures after all alternative therapies have been exhausted.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K021563

Prescription Use X OR Over-The-Counter Use ___
(per 21 CFR 801.109)